

Remarks

Applicants respectfully request reconsideration of the present application in view of the amendments set forth above and the remarks below.

The pending Office Action addresses and rejects claims 1-6, 11-13, 15, 24, and 37-38. Claims 1-6, 11-13, 15, 24, and 39-40 are subject to restriction.

Amendments to the Claims

Applicants have previously amended the application to remove “means” language and replace “supporting means” with “a support.” Though “supporting means” was removed from claim 15, “support” was not added. Claim 15 is amended to correct this error. Claim 24 is also amended to correct a typographical error.

Election/Restriction

In the instant Office Action, the Examiner requires restriction of the application to one of the following inventions:

- I. Claims 1-6, 11-13, 15, 24, and 37-38, drawn to a fusion device with a solid vertebral structure, classified in class 606, subclass 61.
- II. Claims 39-40, drawn to an intervertebral device with an inflatable balloon, classified in class 606, subclass 192.

Applicants affirm the election, with traverse, of the Group I claims (i.e., claims 1-6, 11-13, 15, 24, and 37-38). The Examiner argues that inventions are related as subcombinations that are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. Applicants submit that Group I and Group II claims do overlap in scope as they both recite “a body having a proximal portion along a major axis of the body and a distal portion along the major axis and wherein the body defines a conduit substantially parallel to the major axis, said conduit extending throughout the body.”

Further, Applicants submit that Group II is not a subcombination but rather a species of Group I. Independent claim 1 is generic to all species because it does not include any material element additional to those recited in the species' claims, and it comprehends the organization covered in each species. MPEP § 806.04(d). Dependant claim 11 recites an intervertebral fusion device wherein the support consists of a balloon. A "support" is generic and a balloon is one type of support. The Group II claims recite a type of balloon support. Therefore, the Group II claims are a species of generic claim 1 combined with dependant claim 11.

Claim Rejections Pursuant to 35 U.S.C. § 102

Claims 1-6, 15, and 37

The Examiner rejects claims 1-6, 15, and 37 as being anticipated under 35 U.S.C. §102(b) by U.S. Patent No. 6,375,655 of Zdeblick *et al.* ("Zdeblick"). Referring to Figures 2 and 9 of Zdeblick, the Examiner states that Zdeblick discloses a fusion device for use in the spine, comprising a body having a proximal portion and a distal portion that defines a conduit. The Examiner states that the conduit is defined as an artificial channel or passage that is substantially parallel to the major axis. The Examiner further states that Zdeblick discloses a supporting means capable of supporting vertebrae in a distracted position while the vertebrae fuse. The Examiner states that the "open inside" of the supporting means is considered a conduit in fluid communication with the conduit of the body. Applicants respectfully disagree.

Applicants previously amended independent claim 1 to highlight that the conduit extends throughout the body of the device as defined within the specification. In response, the Examiner has previously admitted that Zdeblick does not teach a body with a "conduit throughout" the body as required by Applicants' independent claim 1. (Office action dated December 28, 2006, page 3 and interview dated March 30th, 2007). Thus, Applicants submit that claim 1 is novel in view of Zdeblick.

The Examiner previously relied on U.S. Patent No. 6,752,809 of Gorek to remedy this deficiency of Zdeblick. Applicants successfully overcame the rejection by demonstrating that a person having ordinary skill in the art would not be motivated to modify Zdeblick in view of Gorek. Though the Applicants had amended claims in light of the previous office action, the relevant portion of the claims teaching a "conduit throughout" was not modified. Thus, the

Examiner cannot state that Zdeblick alone teaches each and every element of the device defined in claims 1-6, 15, and 37, when the examiner needed to rely on Gorek in the past to remedy deficiencies in Zdeblick.

Further, the Examiner erroneously concludes that Zdeblick teaches a conduit in a body which is in fluid communication with a conduit in a support as is recited in Applicants' claim 1. Applicants respectfully submit that Zdeblick's implant driver lacks any type of conduit.

Zdeblick discloses and illustrates (in Figure 9) that the implant driver (50) is comprised of a shaft (51) and sleeve (52) concentrically disposed about the shaft. The shaft (51) does not have a conduit or any means at the proximal or distal end to fluidly communicate with any conduit in a support. The shaft (51) mates with a conical chamber (67) defined on the inner wall of the sleeve. (See column 9, line 65 to column 10, line 5.) Thus, the sleeve cannot define a conduit because (1) it mates with the shaft and (2) it does not allow fluid communication with a conduit in a support.

The Examiner states "the open inside of the supporting means is considered in fluid communication with the conduit of the body." However, in view of the discussion above, this is incorrect because the implant driver lacks a conduit. The implant driver (50) does not have a conduit which is in fluid communication with a conduit in a support. Rather Zdeblick's implant driver merely has a "hinge slot" which supports a pair of tongs for gripping an interbody fusion device. This slot is in no way able to communicate fluidly with the fusion device or the proximal end of the implant driver. (See Zdeblick for example, at column 9, lines 42-56.)

In view of all the above enumerated deficiencies in Zdeblick, and further in view of Applicants' discussion of the novel features of claims 1-6, 15, and 37, Applicants respectfully submit that the Examiner's rejection be withdrawn and pending claims 1-6, 15, and 37 be allowed.

Claim Rejections Pursuant to 35 U.S.C. § 103

Claims 11-13 and 24

The Office Action also addresses and rejects claims 11-13 and 24 under 35 U.S.C. § 103 as being obvious over Zdeblick in view of U.S. Pub 2003/0028251 of Mathews. The Examiner argues that Zdeblick discloses the claimed invention "except for a supporting means that is a balloon that and materials, used in the supporting implant or in the balloon may facilitate bone growth, or a flowable material (sic)." The Examiner relies on Mathews to remedy these deficiencies, alleging that Mathews teaches a spinal device that is capable of being a support device as a balloon and that

may be made of bioreactive, or bioresorbable material and that is flowable. Applicants respectfully disagree.

First, Applicants respectfully submit that claims 11-13 and 24 are allowable for the same reasons that claim 1 is allowable, as set forth above, since claims 11-13 and 24 depend from independent claim 1 and include all of the limitations of claim 1.

Furthermore, Mathews does not remedy the deficiencies of Zdeblick with respect to Applicants' claims 11-13 and 24 because Mathews does not teach a support having an outlet, as recited in Applicants' claims 1 and 24. Mathews also fails to disclose a balloon which is resorbable, and merely states that the material which fills the balloon can be resorbable. In addition, Mathews teaches a balloon that is used to create one or more voids which are filled by another mechanism. Applicants' balloon is itself used via the fluid conduit to deliver material.

Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of claims 11-13 and 24 in view of the arguments above.

Claim 38

The Office Action also addresses and rejects claim 38 under 35 U.S.C. § 103 as being obvious over Zdeblick in view of U.S. Patent No. 6,258,094 of Nicholson *et al.* ("Nicholson"). The Examiner argues that Zdeblick discloses the claimed invention "except for specifically a support that is biodegradable." The Examiner relies on Nicholson to remedy these deficiencies, alleging that Nicholson teaches a "vertebrae implant...having a biodegradable material." Applicants respectfully disagree.

First, Applicants respectfully submit that claim 38 is allowable for the same reasons that claim 1 is allowable, as set forth above, since claims 38 depends from independent claim 1 and includes all of the limitations of claim 1.

In addition, the Examiner has overlooked the fact that Nicholson does not teach an intervertebral implant having biodegradable material. Nicholson discloses that "a relatively thin external shell of a synthetic material can be provided for enclosing" the intervertebral implant. Nicholson goes on to state that the shell can be composed of biodegradable material (see column 12, lines 25-40). However, Nicholson does not disclose an intervertebral support being made of biodegradable material - only the shell is biodegradable.

Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of claim 38 in view of the arguments above.

Conclusion

In view of the foregoing, Applicants respectfully request that the Examiner allow all pending claims.

Respectfully submitted,

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